UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

HOWMEDICA OSTEONICS CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	**3:02-CV-321**
	)	
TRANQUIL PROSPECTS, LTD.	)	
	)	
Defendant.	)	

MEMORANDUM, ORDER & OPINION

This matter is before the Court on the First Motion for Summary Judgment (*Amended*) (Docket No. 97) filed by the Plaintiff, Howmedica Osteonics Corporation, on April 14, 2006 and on the Motion for Summary Judgment (Docket No. 103) filed by the Defendant, Tranquil Prospects, Ltd., on April 17, 2006. Oral arguments were heard on these motions in South Bend, Indiana on August 24, 2006, and the issues have been fully briefed.

I. JURISDICTION

Howmedica Osteonics Corporation ("Howmedica") is a New Jersey corporation with its principal place of business in New Jersey. Complaint ¶ 1. Howmedica is a wholly-owned subsidiary of the Stryker Corporation of Kalamazoo, Michigan, which designs, manufactures, and markets orthopedic implants for use in reconstructing various joints in the human body, including hip implants.

Tranquil Prospects, Inc. ("Tranquil") is an international business corporation

incorporated in the British Virgin Islands with a place of business at Tortola, British Virgin Islands. *Id.* at ¶ 2. Tranquil is the owner of United States Patents Nos. 4,636,214 ("the '214 patent") and 5,222,985 ("the '985 patent"), both entitled "Implantation of Articulating Joint Prosthesis."

Subject matter jurisdiction is conferred on this Court pursuant to 28 U.S.C. § 1338(a). Venue is based on 28 U.S.C. §§ 1331(d).

II. PROCEDURAL HISTORY

Howmedica filed this suit on May 1, 2002, alleging non-infringement and invalidity of the '214 and '985 patents. Complaint at 1. Tranquil counterclaimed for infringement. The Court entered a claim construction order on September 25, 2003, determining that ambiguities in the term "transverse sectional dimensions" rendered the claims of both patents indefinite. *See,* Docket No. 46. In the same order, the Court construed the '985 claims to require a coating on the prosthetic before implantation. *Id*. Then, on January 14, 2004, the Court ordered that the asserted claims of the '214 and '985 patents were invalid and entered judgment pursuant to Rule 54(b) in favor of Howmedica. That judgment was appealed on February 3, 3004, and on April 1, 2005, the Federal Circuit reversed in part, vacated in part, and remanded the case to this Court for further proceedings.

III. PATENTS AT ISSUE

A. The '214 and '985 Patents

Charles A. Homsey ("Homsey"), the inventor, filed the '214 patent with the United States Patent and Trademark Office ("USPTO") on October 17, 1985, and the '214 patent issued on January 13, 1987. The '214 patent is an "intramedullary prosthesis device and the method of orthopedic implantation of the prosthesis device, particularly for a hip prosthesis." '214 Patent Abstract. It is designed to "utilze an elongate stem undersized precisely with respect to a precisely formed stem socket defined by cortical bone or dense cancellous bone of a long bone. Bone cement is used to fill the void area between the stem of the prosthesis device and the precisely formed stem socket." '214 Patent Abstract.

Homsey also invented the '985 patent and filed the '985 patent application with the USPTO on November 17, 1988. The '985 patent issued on June 29, 1993 and is directed to an intramedullary prosthesis particularly for a hip prosthesis. '985 Patent Abstract. The '985 patent prosthesis "utilizes a tapered elongate stem undersized precisely with respect to a precisely formed stem socket in the medullary canal with the stem socket defined by cortical bone or dense cancellous bone of a long bone." *Id.* "A layer of coating material surrounds the undersized stem along its entire length and is of a generally uniform thickness along the entire length of the stem with the coating material filling the void between the stem of the prosthesis and the precisely formed stem socket."

Id. The '214 and '985 patents have identical written descriptions.[1]

The type of intramedullary prosthesis described in the '214 and '985 patents is used to replace the ball of the hip joint; during surgery, the "patient's ball and part of the neck from the upper end of the femoral bone" is removed. '214 patent, col. 1, ll. 15-25. "A metal prosthesis implant, having a ball, neck, and stem, was then inserted into the medullary canal of the femur. Prior to such insertion, the more centrally positioned, softer, cancellous bone of the medullary canal has been rasped to form a bone cavity which was able to accept therein the stem of the prosthesis." *Id.*

To increase stability and load transfer to allow patients a full range of motion without pain, while at the same time preventing fracturing of the femoral bone during insertion of the stem into the prepared stem socket within the medullary canal, the '214 and '985 patents introduced "methods and apparatus for installation of an intramedullary prosthetic that is substantially the same size and shape as the medullary canal, as defined by the softer cortical bone or cortex." *Howmedica Osteonics Corp. v. Tranquil Prospects*, 401 F.3d 1367, 1369 (Fed. Cir. 2005) (*citing* '214 patent, col.3, ll. 50-58). The result is that the '214 and '985 patents provide: "(1) an adequate initial stabilization within the stem socket, (2) an enduring subsequent stem stabilization, (3) a distributed longitudinal load transfer, (4) an improved load transfer between stem and surrounding

[1]Like the Federal Circuit, to avoid redundancy, this Court will also provide citations to the written description of only the '214 patent when discussing issues pertinent to both the '214 and '985 patents.

hard cancellous bone and cortical bone, and (5) reduced localized stress zones in the bone opposite to and facing the entire stem." '214 patent, col. 3, ll. 42-49.

The '214 patent contains four claims. Claim 1 of the '214 patent is representative of the claim language at issue in that patent, and states:

> 1. A method of surgical orthopedic implantation of an intramedullary prosthesis device having an elongate stem with distal and proximate ends into the medullary canal of a long bone defined by the cortex of a long bone and comprising the steps of:
>
> forming in said medullary canal a stem socket;
>
> sizing the stem socket with an appropriately sized tool to form a socket defined substantially by the inner periphery of compact bone formed by cortical or dense cancellous bone, said stem having transverse sectional dimensions along substantially its entire length which are undersized with respect to adjacent corresponding transverse sectional dimensions of said stem socket;
>
> then injecting bone cement in the completed stem socket; and
>
> finally pushing said stem into said stem socket with said bone cement therein surrounding the stem for its entire length including its distal and proximate ends whereby said cement forms a liner around the outer surface of said stem between the stem and the adjacent compact bone, the transverse sectional dimensions of the liner and stem constituting at least around seventy percent (70%) of the corresponding transverse sectional dimensions of the long bone defined by cortical bone or metaphyseal and epiphyseal segments of said long bone, and at least around ninety percent (90%) of the corresponding transverse sectional dimensions of the long bone defined by cortical bone of the diaphyseal segment of said long bone.

'214 Patent.

The '985 patent contains nine claims. Claim 1 of the '985 patent is representative of the claim language at issue in that patent, and states:

> 1. An intramedullary prosthesis comprising:
>
> an elongate stem having distal and proximal ends and adapted to be forcibly inserted within an elongated stem socket having its inner periphery defined by compact bone formed by cortical bone or dense cancellous bone of a long bone, said stem having transverse sectional dimensions along substantially its entire length undersized with respect to corresponding transverse sectional dimensions of said socket;
>
> a layer of coating material surrounding said undersized stem along its entire length including its distal and proximal ends and covering substantially the entire outer surface of said stem, the coated stem having transverse sectional dimensions constituting at least around seventy percent (70%) of the transverse sectional dimensions of said medullary canal defined by cortical bone of the metaphyseal and epiphyseal segments of said long bone, and at least around ninety percent (90%) of the corresponding transverse sectional dimensions of the long bone defined by the cortical bone of the diaphyseal segment of said long bone;
>
> said layer of coating material being of a generally uniform predetermined thickness along the entire length of the stem sufficient to provide improved load transfer between the stem and the adjacent compact bone formed by hard cancellous bone and hard cortical bone, said tapered stem being of minimal cross-sectional area adjacent said distal end and of maximum cross-sectional area adjacent said proximal end with said generally uniform thickness coating material progressively increasing in cross-sectional area from said distal end to said proximal end of said stem.

'985 Patent.

The description of the preferred embodiments is the same for the '214 and '985 patents,[2] stating:

> With particular reference to the drawings, the prosthesis of this invention, generally designated as (10), has a stem (18) adapted for insertion into the

[2]Because the preferred embodiments and the drawings are identical, the Court will only reference the '214 patent.

> medullary canal (28) (FIG. 6) of a femur (27). Prosthesis (10) is illustrated as being a hip joint prosthesis or femoral ball prosthesis. However, the portion of the description relating to stem (18) and the stem's interrelation with and its fixation within the medullary canal (28) would be equally applicable to other articulating joint prostheses.
>
> With particular reference to FIGS. 1-4, prosthesis (10) includes a ball (12), a flange (16), and a neck (14) which extends therebetween. A stem (18) comprises a shank portion which extends away from the opposite side of flange (16) substantially at a right angle thereto. In side elevation, as shown in FIG. 1, stem (18) is curved at its proximate end and tapers down at its distal end to an annular flange (20).
>
> Flange (20) is shown as having a circular transverse section and extends radially outwardly by slightly less than 2 millimeters beyond the main body of stem (18). The proximate end of stem (18) is relatively flat and has an inner surface (22) which is rounded and an outer surface (24) which is flat but with rounded edges, as shown in FIGS. 3-4. Instead of having a circular section, flange (20) can have an oval section.
>
> It should be understood that the improved stem (18) should be made in at least three distinct shapes, each shape having a set of distinct dimensions designated in FIGS. 1, 3 and 4 by letters a through g. It has been found in practice that three distinct shapes for a femoral prosthesis will accommodate most shapes of femurs (27) normally encountered in human skeletons. Accordingly, such three distinct shapes for implant (10) can be manufactured in advance and made available to the surgeons, together with instructions for preparing corresponding stem sockets, as will be subsequently described.

‘214 Patent, Description of Preferred Embodiments.

Figures 1, 3, 5 and 6 of the ‘214 patent [and the ‘985 patent] are reproduced below:

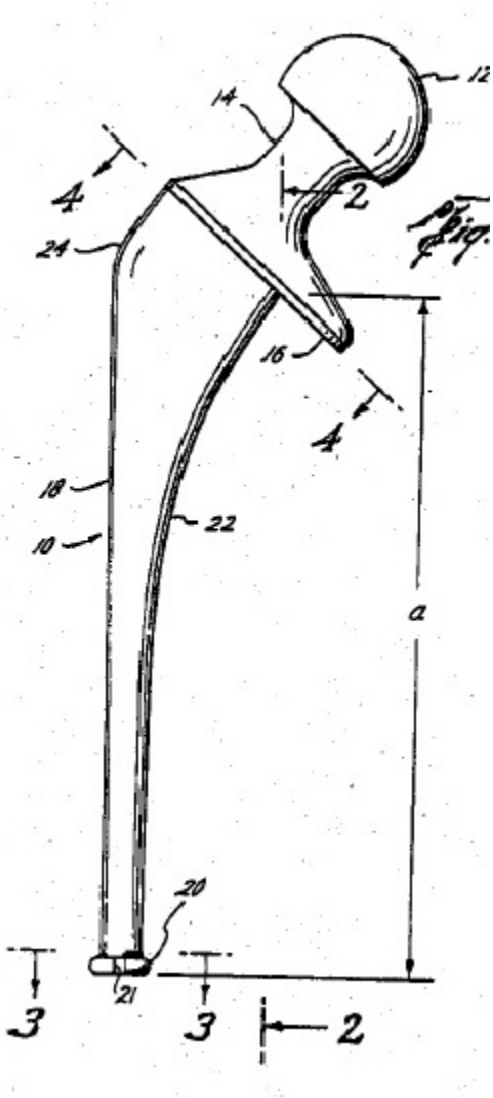


Figure 1

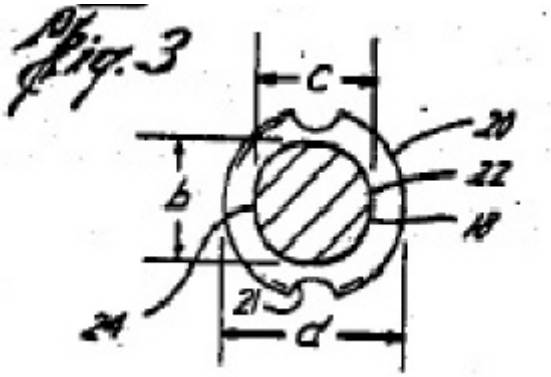
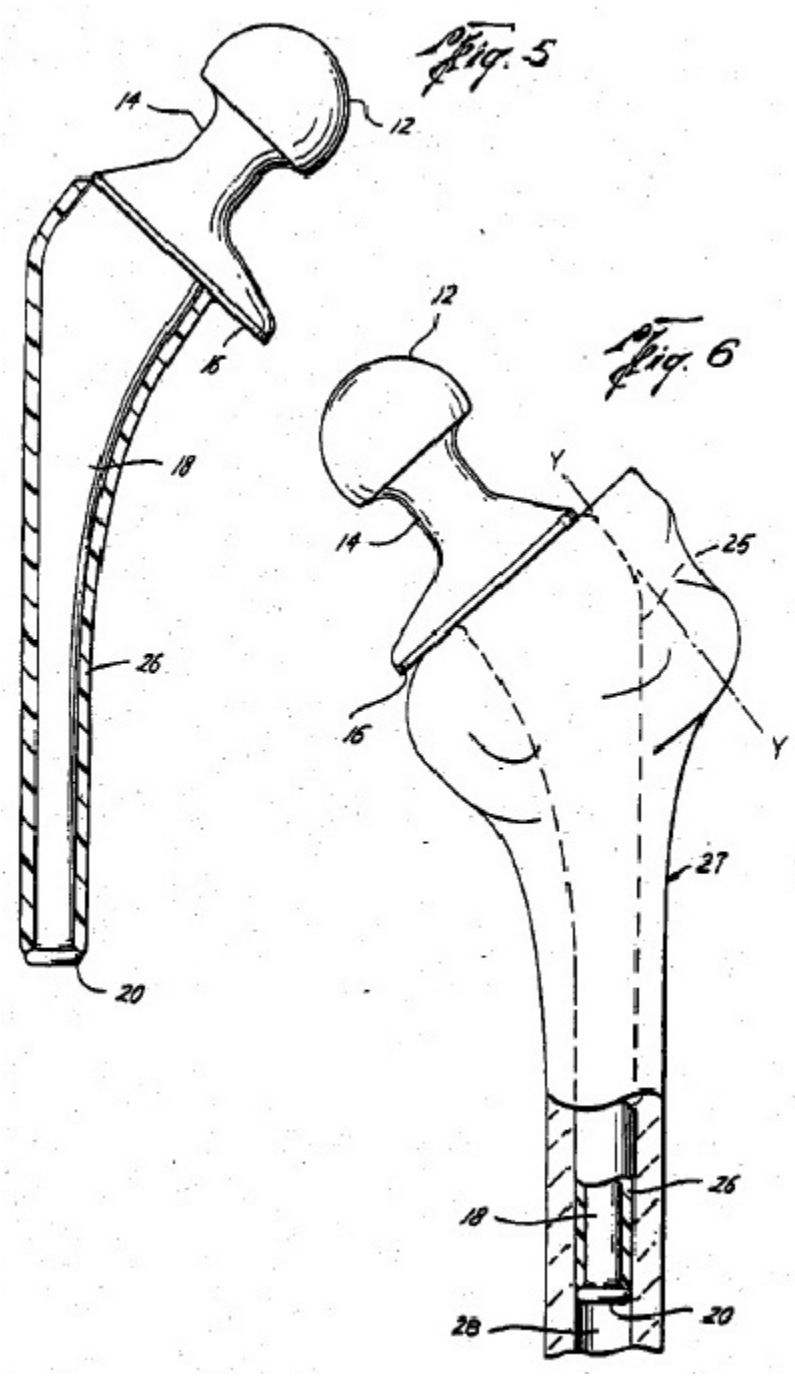


Figure 3



Figures 5 & 6

B. Howmedica's Accused Products

Dr. William Hopkinson, Tranquil's expert, identified two products sold by Howmedica as allegedly infringing products: the hip stem implants sold under the names "Strata" and "Omnifit." On August 11, 2006, Tranquil withdrew its reliance on an analysis of the Howmedica Omnifit hip replacement prosthesis and the statements related thereto.[3] *See*, Docket Nos. 123 and 125. Tranquil argues, however, that "during this case, Howmedica has identified over 20 different models of hip stems implanted using cement." Docket No. 98 at 7. According to Tranquil, these twenty different models of hip stems implanted using cement are also allegedly infringing products.[4]

C. Relevant Claim Construction

The claims of the '214 and '985 patents reference the medullary canal, which is a portion of the femur in which a stem socket is placed as part of installing the prosthetic device. A stem socket – having an elongated stem inserted within – is inserted into the medullary canal. This Court previously construed the term "medullary canal defined by cortical bone of the metaphyseal and epiphyseal segments of said long bone" as analogous with the description of the long bone in a treatise by Ross, Rommell, and

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[3]The analysis is Exhibit J which is attached to the Expert Report of Dr. William J. Hopkinson and is found in Exhibit D to the Declaration of Samantha Kameros [docket No. 94, filed 04/03/2006]. *See*, Docket Nos. 123 and 125.

[4]As of the date of this Order, the twenty different models of hip stems implanted using cement have not yet been identified by Tranquil.

Kaye.[5] The Court concluded that the medullary canal does not extend beyond the thick wall of the compact bone (which may or may not be lined with spongy bone). Docket No. 46 at 8.

The claims of the '214 and '985 patents require that the "transverse sectional dimensions" of the coated prosthesis constitute certain percentages of the "transverse sectional dimensions" of the medullary canal, defined by the cortical bone. '214 patent, col. 9, ll. 26-36; '985 patent, col. 9, ll. 17-26. The Federal Circuit held that "one of ordinary skill in the art would readily ascertain from the written description of the patents that the 'transverse sectional dimension' calls for a two-dimensional measurement" and that the invention "shapes the prosthesis to fit snugly inside the medullary canal." *Howmedica*, 401 F.3d at 1371-72. The Federal Circuit further stated, "[t]o satisfy the definiteness requirement, the term 'transverse sectional dimensions' also need not specify percentage limitations nor the locations along the prosthesis that the percentage must satisfy to constitute a proper dimensional fit." *Id*. at 1373. The Federal Circuit stated, "the patent clearly specifies that '[t]he present invention is rooted in the recognition of the importance and criticality of the stem's traverse sectional dimensions, along the entire

[5]*See*, Ross, Michael H., Lynn J. Rommel & Gordon I. Kaye. *Histology: A Text and Atlas*. 3d ed. Williams & Wilkins 1995, p. 153. ("A typical long bone (such as a femur) contains a shaft called the diaphysis. The diaphysis contains a large marrow or medullary canal. This cavity is surrounded by a thick-walled tube of compact bone. The inside of the compact bone may itself be lined with spongy bone. At the ends (the 'epiphyses') of the long bone, there is additional spongy bone and an outer lining of compact bone. At the very ends of the long bone (at the 'diaphysis') is the metaphysis, which is the 'flared' part of the bone.")

length thereof, relative to the corresponding transverse sectional dimensions of the medullary canal. . . .'" *Id*.; quoting '214 patent, col. 3, ll. 33-37 (emphasis added). Based on this analysis, the Federal Circuit construed the term "transverse sectional dimensions" to refer to the cross-sectional area of the prosthesis along the entire length of the portions of the bone specified by the claims." *Id*. at 1375.

The Federal Circuit also stated that the "language of claim 1 can accommodate coating the stem by injecting bone cement into the stem socket before insertion of the prosthesis. This particular coating method could satisfy the 'generally uniform' limitation of claim 1 of the '985 patent." *Id*. at 1374. Further, the Federal Circuit concluded that "claim 1 can cover a prosthesis whose stem is coated by inserting the prosthesis into a canal already charged with bone cement." *Howmedica,* 401 F.3d at 1374-75. This conclusion was reached with the "understanding that the written description of the '985 patent includes references to 'coated' and 'uncoated' stems." *Id*. at 1375. Finally, the Federal Circuit concluded that "[b]ecause claim 1 is an apparatus claim without process limitations . . . [there is] no difference in 'coating' for a stem covered with bone cement before insertion and a stem covered with bone cement upon insertion into the stem socket." *Id*. at 1375.

IV. STANDARD OF REVIEW

Pursuant to Rule 56(c) of the Federal Rules of Civil Procedure, summary judgment is proper only if there is no genuine issue as to any material fact, the trial court has

properly construed the claims, and the moving party is entitled to judgment as a matter of law. *Lockwood v. American Airlines Inc.*, 107 F.3d 1565, 1576 (Fed. Cir. 1997). *See also Nebraska v. Wyoming*, 507 U.S. 584, 590 (1993); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). In deciding a motion for summary judgment, a court must view all facts in the light most favorable to the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986); *Nucor Corp. v. Aceros Y Maquilas De Occidente*, 28 F.3d 572, 583 (7th Cir. 1994).

The moving party bears the burden of identifying those portions of "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits" that the moving party believes demonstrate an absence of genuine issue of material fact. *Celotex*, 477 U.S. at 323. Once this burden is met, the nonmoving party "must set forth specific facts showing that there is a genuine issue for trial." FED. R. CIV. P. 56(e); *Becker v. Tenenbaum-Hill Assocs., Inc.*, 914 F.2d 107, 110 (7th Cir. 1990); *Schroeder v. Lufthansa German Airlines*, 875 F.2d 613, 620 (7th Cir. 1989). "[A] party who bears the burden of proof on a particular issue may not rest on its pleading, but must affirmatively demonstrate, by specific factual allegations, that there is a genuine issue of material fact which requires trial." *Beard v. Whitley County REMC*, 840 F.2d 405, 410 (7th Cir. 1988). Therefore, if a party fails to establish the existence of an essential element on which the party bears the burden of proof at trial, summary judgment is proper.

When parties file cross motions for summary judgment, each motion must be assessed independently, and denial of one does not necessitate the grant of the other. *M. Snower & Co. v. United States*, 140 F.2d 367, 369 (7th Cir. 1944). Rather, each motion evidences only that the movant believes it is entitled to judgment as a matter of law on the issues within its motion and that trial is the appropriate course of action if the court disagrees with that assessment. *Miller v. LeSea Broadcasting, Inc.*, 87 F.3d 224, 230 (7th Cir. 1996).

V. DISCUSSION

Howmedica has filed a motion for summary judgment of noninfringement of claims 1, 4, 5, and 6 of the '985 patent and claim 2 of the '214 patent. *See* Docket No. 98. Tranquil has filed a motion for summary judgment of direct, literal infringement of the claims 1, 4, 5, and 6 of the '985 patent.[6] *See* Docket No. 103. Tranquil also asserts that it is entitled to summary judgment that the asserted claims of the '985 patent are not anticipated by the HS-1 putative prior art. *Id*. The Court will address each of these issues in turn.

A. Tranquil's Virtual Surgery

As a threshold matter, Howmedica contends that Tranquil's "virtual surgery" is insufficient to establish infringement of the asserted claims of the '214 and '985 patents. Specifically, Howmedica asserts that the "'virtual surgery' is neither scientifically sound,

[6]Tranquil does not seek summary judgment of infringement with respect to claim 2 of the '214 patent.

nor is it representative of the result of an actual surgical implantation of a Howmedica hip stem in an actual patient. . . . [the "virtual surgery"] provides no basis for a conclusion that *any* Howmedica hip stem, let alone *all* of Howmedica's accused stems, would meet the limitations of the asserted claims in actual practice." Docket No. 98 (emphasis in original). Accordingly, Howmedica contends that the "virtual surgery" relied on by Tranquil as the sole evidence to prove infringement fails to establish a material issue of fact to preclude a finding of noninfringement. Tranquil argues that the "virtual surgery" is competent evidence to establish infringement, and to refute Howmedica's arguments, Tranquil relies on the expert report of its technical expert, Dr. William Hopkinson ("Dr. Hopkinson"), attached as Exhibit D to the Kameros declaration submitted by Howmedica.

Dr. Hopkinson's expert report, however, is unsworn and unverified. Federal Rule of Civil Procedure 56(e) states in part:

> Supporting and opposing affidavits shall be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein. Sworn or certified copies of all papers or parts thereof referred to in an affidavit shall be attached thereto or served therewith.

Accordingly, an unsworn and unverified expert report is not Rule 56 evidence that may be relied upon to overcome a motion for summary judgment. *See, Adickes v. S. H. Kress & Co.,* 389 U.S. 144, 158 n. 17 (1970) (unsworn statement does not meet the requirements of Rule 56(e)); *Provident Life and Acc. Ins. Co. v. Goel*, 274 F.3d 984, 1000 (5th Cir. 2001) (stating "[u]nsworn expert reports . . . do not qualify as affidavits or otherwise

admissible evidence for [the] purpose of Rule 56, and may be disregarded by the court when ruling on a motion for summary judgment."[7]); *Fowle v. C & C Cola, a Div. of ITT-Continental Baking*, 868 F.2d 59, 67 (3d Cir. 1989) (stating that where the substance of a report is not sworn by the alleged expert, "the purported expert's report is not competent to be considered on a motion for summary judgment"). Accordingly, the unsworn expert report of Dr. Hopkinson is insufficient to support an infringement analysis. However, rather than deciding this case on hypertechnical grounds, the Court will decide this case on its merits.

A. Patent Infringement

Howmedica asserts that even if Tranquil's "virtual surgery" is reliable, Tranquil failed to demonstrate that Howmedica's Strata or other stems infringe literally or under the doctrine of equivalents. In contrast, Tranquil contends that it is entitled to summary judgment that Howmedica's products directly and literally infringe the '985 patent.

Patent infringement occurs when a person "without authority makes, uses, offers to sell, or sells any patent invention, within the United States or imports into the United States any patented invention, during the term of the patent." 35 U.S.C. § 271(a). *See Hoechst-Roussel Pharm., Inc. v. Lehman*, 109 F.3d 756, 759 (Fed. Cir. 1997). The patentee bears the ultimate burden of proving infringement. However, an "accused infringer seeking summary judgment of noninfringement may meet its initial

[7]11 JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE, ¶ 56.14[2][c] (3d 3e. 1997). *Cf. Nissho-Iwai American Corp. v. Kline*, 845 F.2d 1300, 1306 (5th Cir. 1988).

responsibility either by providing evidence that would preclude a finding of infringement, or by showing that the evidence on file fails to establish a material issue of fact essential to the patentee's case." *Novartis Corp. v. Ben Venue Labs., Inc.*, 271 F.3d 1043, 1046 (Fed. Cir. 2001) (*citing Vivid Tech., Inc. v. American Sci. & Eng'g, Inc.*, 200 F.3d 795, 807 (Fed. Cir. 1999)).

Whether the accused device meets each claim limitation is generally an issue of fact. *Pause Tech.*, LLC v. TiVo, Inc., 419 F.3d 1326, 1329 (Fed. Cir. 2005). A trial court cannot reach a conclusive finding of non-infringement if the record shows some evidence supporting a finding of non-infringement and some evidence to the contrary. *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1371 (Fed. Cir. 2004). *See also, Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1323 (Fed. Cir. 2001) (stating that summary judgment of noninfringement is "appropriate when it is apparent that only one conclusion as to infringement could be reached by a reasonable jury").

A finding of patent infringement requires a two-step analytical approach. First, the claims of the patent must be construed as a matter of law to determine their proper scope and meaning. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995). *See also Liquid Dynamics Corp. v. Vaughan Co., Inc.*, 355 F.3d 1361, 1367 (Fed. Cir. 2004); *Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co.*, 308 F.3d 1167, 1176 (Fed. Cir. 2002). *See also* 35 U.S.C. § 271(a). Second, the patentee must demonstrate by a preponderance of the evidence that every claim limitation the claim

asserted to be infringed is present in the accused device, either literally or under the doctrine of equivalents. *Liquid Dynamics*, 355 F.3d at 1367. *See also Pause Tech.,* 419 F.3d at 1329 (asserting that after claim construction is complete, the next step in an infringement analysis is for the court to compare the properly construed claims with the allegedly infringing devices). Step one was completed when the proper meaning and scope of the terms were determined by this Court in its September 25, 2003 claim construction order and by the Federal Circuit in its order, dated March 28, 2005. Accordingly, this Court must now proceed to step two.

1. Direct, Literal Infringement

To establish literal infringement, the allegedly infringing products must contain every limitation set forth in the asserted patent claims. *Konvin Assoc. v. Extech/Exterior Techs*., No. 04-2544, 2006 WL 2460589, *10 (N.D. Ill. Aug. 21, 2006); *Southwall Technologies v. Cardinal IG Co.,* 54 F.3d 1570, 1575 (Fed. Cir. 2005) (*en banc*); *Kenall Mfg. Co. v. Genlyte Thomas Group., LLC*, 439 F.Supp.2d 854, 865 (N.D. Ill. 2006). To prove literal infringement in this case, Tranquil must demonstrate that Howmedica's accused hip stems meet every limitation set forth in claim 1 of the '214 patent and claims 1, 4, 5, and 6 of the '985 patent.

Tranquil has not demonstrated by use of the "virtual surgery" that Howmedica's accused hip stems, and the method of implanting the same, meet every limitation set forth in the asserted claims. Docket No. 98 at 12-13. Specifically, Tranquil has failed to show

that the percentage limitations of the transverse sectional dimensions for each portion of the epiphyseal, metaphyseal, and diaphyseal regions, respectively, in the claims is met along substantially the entire length of the implant for each respective bone portion.

This Court also finds that the Strata stem lacks one element of claim 1 of the '985 patent and claim 2 of the '214 patent: that "the coated stem having transverse sectional dimensions constituting around seventy percent (70%) of the transverse sectional dimensions of said medullary canal defined by cortical bone of the metaphyseal and epiphyseal segments of said long bone, and at least around ninety percent (90%) of the corresponding transverse sectional dimensions of the long bone defined by the cortical bone of the diaphyseal segment of said long bone, ..." '985 patent, col. 9, ll. 17-26.

"Medullary canal" has been construed as follows:

> As to the '985 patent, the Court construes the claim language "medullary canal defined by cortical bone of the metaphyseal and epiphyseal segments of said long bone" as analogous with the description fo the long bone above. Based upon Ross et al.'s definition, and Tranquil's claim language, for the purpose of the '985 Patent, the medullary canal does not extend beyond the thick wall of the compact bone (which may or may not be lined with spongy bone). Since the '214 Patent's claim language does not include the "as defined" qualifications, no further construction is needed of "medullary canal" and for purposes of the '214 Patent as well, the medullary canal does not extend beyond the thick wall of the compact bone (which may or may not be lined with spongy bone).

Howmedica Osteonics Corp. v. Tranquil Prospects, Ltd., 288 F. Supp. 2d 939, 944-45 (N.D. Ind. 2003). Accordingly, the 70% fill requirement applies to all portions of the metaphyseal and epiphyseal segments of the long bone that are bound by the thick wall of

the cortical bone, and the 70% and 90% limitation in the epiphyseal, metaphyseal, and diaphyseal bone regions must be found for all implanted hip stems.[8]

Tranquil argues that the "Federal Circuit's construction that these [70% and 90%] limitations must be met along 'substantially the entire length' for each respective portion of the long bone simply requires 'a reasonable precision.'" Docket No. 104 at 10; Tranquil's Statement of Fact 40. Further, Tranquil asserts that the term "around" only requires close "within reason." Docket No. 104 at 10; Tranquil's Statement of Fact 41.

The Court rejects Tranquil's argument that there is no strict 70% and 90% fit and fill requirement. Patent claim language and claim construction require preciseness and definiteness. This Court is confident that the 70% and 90% limitations mean what they say: 70% and 90%. Accordingly, this Court rejects Tranquil's argument that 84% is "around" 90% and finds that Tranquil has failed to satisfy this requirement.

Additionally, the Court finds that the 70% and 90% limitations must be met along the entire length of the coated stem. This finding is consistent with the Federal Circuit's statement that the "percentage limitations of the 'transverse sectional dimensions' for each portion of the bone specified in the claims must be met along 'substantially the entire length' for each respective portion" of the bone. *Howmedica*, 401 F.3d at 1373.

Tranquil took five measurements at four levels in the diaphyseal region and one

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[8]This Court notes that it's inclusion of the drawing of the long bone, attached as Exhibit A to Docket No. 46, was not a finding that the medullary canal will not extend into the metaphyseal region of every long bone. Rather, the medullary canal is defined as extending the entire length of the long bone.

measurement in what it termed the meta-diaphyseal region. The data points for level one were taken approximately 7-8 centimeters below the proximal end of the implant when inserted into the bone. By Tranquil's own admission at the August 24, 2006 oral argument hearing, no data points were taken above level one. Accordingly, Tranquil has failed to demonstrate that the 70% limitation is met for substantially the entire length as required by claim language and by the Federal Circuit. Because there is no infringement of the independent claim, there is no infringement of the dependent claims. *See, Wahpeton Canvas Co. v. Frontier, Inc*., 870 F.2d 1546, 1553 n. 10 (Fed. Cir. 1989).

Additionally, Tranquil has failed to provide evidence that all of Howmedica's cemented hip implants infringe the asserted claims of the '214 and '985 patents. With the exception of the Omnifit analysis, which has been withdrawn, Tranquil has not provided an analysis of any Howmedica hip implant other than the Strata. Moreover, the Court agrees with Howmedica's statement that "Tranquil has never specifically identified which of Howmedica's prostheses it contends infringes the '985 and/or the '214 Patents, let alone provided any evidence or analysis regarding additional prostheses." Docket No. 98 at 21. Dr. Hopkinson's expert report also fails to specify which Howmedica prosthesis infringe the '214 and '985 patent. This Court declines the apparent invitation to engage in a fishing expedition and issue a catchall opinion. *See United States v. Dunkel*, 927 F.2d 955, 956 (7th Cir. 1991) (per curiam) ("A skeletal 'argument,' really nothing more than an assertion, does not preserve a claim. . . . Judges are not like pigs, hunting for truffles

buried in briefs.").

2. Doctrine of Equivalents

Even where there is no literal infringement, a product or process may infringe "if there is 'equivalence' between the elements of the accused product or process and the claimed element of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.* 520 U.S. 17, 21 (1997). Under the doctrine of equivalents, the product or process must still contain each limitation of the claim to infringe. *Freedman Seating Co. v. American Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005). *See also Aquatex Indus., Inc. v. Techniche Solutions*, 419 F.3d 1374, 1382 (Fed. Cir. 2005) (holding that to constitute infringement under the doctrine of equivalents, the accused product must contain each limitation of the claim or its equivalent).[9]

Because each limitation contained in a patent claim is material to defining the scope of the patented invention, a doctrine of equivalents analysis must be applied to individual claim limitations, not to the invention as a whole. *Warner-Jenkinson Co.,* 520 U.S. at 40. An element is equivalent if the differences between the element and the claim limitation are insubstantial to one of ordinary skill in the art. *Id.* The analysis of whether differences between the accused product and the claim limitation are "insubstantial" is

[9]The doctrine of equivalents is related to but separate from the notion of equivalency contained in 35 U.S.C. § 112, ¶ 6. "Section 112, paragraph 6, plays no role in determining whether an equivalent function is performed by the accused device under the doctrine of equivalents." *Pennwalt Corp. v. Durand-Wayland, Inc.*, 833 F.2d 931, 934 (Fed. Cir. 1987) (*en banc*).

"whether the element in the accused device 'performs substantially the same function in substantially the same way to obtain the same result' as the claim limitation." *Aquatex*, 419 F.3d at 1382; quoting *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950). *See also Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 543 U.S. 722, 733 (2002) (stating that the doctrine of equivalents "allows the patentee to claim those insubstantial alterations that were not captured in the drafting of the original patent claim but which could be created through trivial changes.").

Howmedica contends that to the extent Tranquil tries to overcome the deficiencies discussed regarding literal infringement "by arguing infringement under the doctrine of equivalents, such argument should also fail." Docket No. 98 at 19. Further, Howmedica stated, "Tranquil has provided no evidence to support a doctrine of equivalents claim except for paragraph 9(g)(ix) of Dr. Hopkinson's expert report which states:

> ix. I understand that, even if an accused product does not satisfy the elements of a patent claim literally, it is still possible for that product to infringe that claim under the doctrine of equivalents, so long as the accused product contains the equivalents of any missing element. I have been informed that an equivalent for infringement purposes is something that performs substantially the same thing in substantially the same way to obtain the same result. In this case, should the foregoing analysis be found not to establish literal infringement, it is certainly sufficient to establish infringement under the doctrine of equivalents, as the percentage fill resulting from the implantation of the accused prosthesis is indistinguishable in terms of function, way and result from the patented invention.

Docket No. 98 at 19-20 (quoting Kameros Decl. Exh. D, ¶9(g)(ix)). Howmedica asserts

that, as a matter of law, "Dr. Hopkinson's statement fails to provide the necessary evidentiary basis to support a claim that there is a genuine issue of material fact on the doctrine of equivalents." Docket No. 98 at 20.

This Court has scoured the record to find Tranquil's response to Howmedica's motion for summary judgment on this issue. The only statement this Court located was contained in footnote 1 to Tranquil's Memorandum in Support of its Motion for Partial Summary Judgment (Docket No. 104).[10] There, Tranquil stated that it "also maintains its counterclaims of infringement of the claims of its other patent in suit, U.S. Patent No. 4,636,214, of indirect infringement, and infringement under the doctrine of equivalents. However, those counterclaims are not the subject of this motion." Docket No. 104 at 6. What Tranquil misses, however, is that infringement under the doctrine of equivalents *was* the subject of Howmedica's motion for summary judgment. Additionally, Dr. Hopkinson's statement alone is insufficient to raise a genuine issue of material fact for trial because it is simply a conclusory expert statement devoid of facts upon which the conclusions were reached. *See, Phillips Petroleum Co. v. Huntsman Polymers Corp*., 157 F.3d 866, 876 (Fed. Cir. 1998). By failing to set forth specific facts showing that there is a genuine issue for trial, Tranquil failed to carry its burden on this issue.

3. Induced Infringement

Even where a party does not directly infringe, that party may still be liable for

[10]Tranquil's memorandum in support of its motion for partial summary judgment also served as its response to Howmedica's motion for summary judgment. *See* Docket No. 108 fn. 1.

inducement or contributory infringement of a claim under 35 U.S.C. §§ 271(b) and (c).[11] To succeed under this theory, "'the patentee must show, first that there has been direct infringement' and 'second, that the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement.'" *MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp*., 420 F.3d 1369, 1378 (Fed. Cir. 2005) (quoting *Minn. Mining & Mfg. Co. v. Chemque, Inc*., 303 F.3d 1294, 1304-05 (Fed. Cir. 2002)). As contributory infringement, liability for active inducement requires direct infringement by someone other than the inducer. *Linear Technology Corp. v. Impala Linear Corp*., 379 F.3d 1311, 1326 (Fed. Cir. 2004). *See also Joy Techs., Inc. v. Flakt, Inc.,* 6 F.3d 770, 774 (Fed. Cir. 1993) (stating "[l[iability for either active inducement of infringement or for contributory infringement is dependent upon the existence of direct infringement").

Howmedica argues that because no individual at Howmedica practices orthopedic surgery or hip implant surgery, Howmedica cannot directly infringe claim 2 of the '214 patent. Docket No. 98 at 16. Rather, according to Howmedica, "Tranquil must first show that there is direct infringement of claim 2 by an actual orthopedic surgeon implanting an accused Howmedica hip implant practicing a surgical method taught by Howmedica." *Id*. Howmedica asserts that, "with respect to the issue of whether or not it induces infringement of claim 2 of the '214 Patent, Tranquil has raised no genuine issue of material fact on this issue to preclude summary judgment, indeed Tranquil has produced

[11]35 U.S.C. § 271(b) states: "[w]hoever actively induces infringement of a patent shall be liable as an infringer."

no evidence to demonstrate that Howmedica has induced infringement." Docket No. 108 at 9.

Alternatively, Tranquil contends that Howmedica induces infringement by teaching orthopedic surgeons to practice the claimed method. Tranquil states only that "[i]t is beyond dispute that Howmedica prepares and disseminates surgical protocols to surgeons to educate surgeons as to the proper method to sue when implanting Howmedica prostheses." Docket No. 104 at 18 (citing Tranquil's Statement of Fact 51). Accordingly, Tranquil contends that this raises at least an issue of fact regarding Howmedica's induced infringement of the claims of the '214 patent.

Claim 2 of the '214 patent provides in part:

> pushing said stem into said socket with said bone cement therein surrounding the stem for its entire length including its distal and proximate ends and forming a cement liner between the stem and the adjacent bone forming the socket, the transverse sectional dimensions of the liner and stem constituting at least seventy percent (70%) of the transverse sectional dimensions of said medullary canal of the metaphyseal and epiphyseal segments of said femur, and at least ninety (90%) of the transverse sectional dimensions of the said medullary canal of the diaphyseal segment of said femur.

'214 patent.

Tranquil has failed to demonstrate precisely how it proposes to prove a disputed fact with admissible evidence. *See DDI Seamless Cylinder Int'l, Inc. v. Gen. Fire Extinguisher Corp.*, 14 F.3d 1163, 1168 (7th Cir. 1994) ("An issue must be pressed, must be argued and supported; a bare conclusion is not enough."). Here, there is no evidence

that Howmedica teaches surgeons to practice the claim limitation in claim 2 of the '214 patent in its surgical protocols or in any other information provided by Howmedica to surgeons using and implanting Howmedica hip stems. Likewise, Tranquil has failed to present any evidence that when a surgeon follows Howmedica's surgical protocols, that the surgeon would, in effect, practice claim 2 of the '214 patent or that an actual orthopedic surgeon implanting Howmedica hip stems practices the method set forth in claim 2. By failing to set forth specific facts showing that there is a genuine issue for trial, Tranquil failed to carry its burden on this issue.

B. Anticipation

Under 35 U.S.C. § 102, each and every element of the claimed invention must be disclosed, either expressly or inherently, in a single prior art reference to invalidate a patent by anticipation.[12] *Telefex, Inc. v. Ficosa North Am. Corp.,* 299 F.3d 1313, 1335 (Fed. Cir. 2002); *Bristol-Myers Squibb Co. v. Ben Venue Labs.,* 246 F.3d 1368, 1373 (Fed. Cir. 2001); *Atlas Powder Co. v. Ireco, Inc*., 190 F.3d 1342, 1346 (Fed. Cir. 1999).

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[12]Anticipation is a question of fact, but it may be decided on summary judgment where there are no genuine disputes as to whether the limitations of the claimed invention are disclosed by the prior art reference(s). *Minnesota Mining & Mfg. v. Chemque, Inc.,* 303 F.3d 1292, 1301 (Fed. Cir. 2002); *Hazani v. U.S. Intern. Trade Com'n*, 126 F.3d 1473, 1477 (Fed. Cir. 1997). *See Atlas Powder Co. v. Ireco, Inc*., 190 F.3d 1342, 1346 (Fed. Cir. 1999) (stating when considering a question of anticipation, the scope and content of the prior art and what it teaches are questions of fact). In determining whether a genuine issue of material fact exists, this Court must view the evidence in the light most favorable to the nonmoving party and resolve all doubts in its favor. *Anderson*, 477 U.S. at 255.

Anticipation requires that "the four corners of a single, prior art document describe every element of the claimed invention, expressly or inherently, such that a person of ordinary skill in the art could practice the invention without undue experimentation." *Advanced Display Systems, Inc. v. Kent State University*, 212 F.3d 1272, 1282 (Fed. Cir. 2000). *See also C.R. Bard, Inc. v. M3 Sys., Inc.,* 157 F.3d 1340, 1349 (Fed. Cir. 1998) (stating that if any claimed element is missing from this single prior art reference, it cannot anticipate the claimed invention). The invention must be new or novel, and a challenger cannot prove anticipation "by combining more than one reference to show the elements of the claimed invention." I DONALD S. CHISUM, CHISUM ON PATENTS § 3.02 (Rel. No. 71, Sept. 1999).

A prior art reference may anticipate when "the claim limitation or limitations not expressly found in that reference are nonetheless inherent in it."[13] *Atlas Powder Co.*, 190 F.3d at 1347. Inherency in a prior art reference is established when the claim feature is the "'natural result' flowing from the reference's explicitly explicated limitations." *Eli Lilly and Co.*, 251 F.3d at 970 (*citing Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 2001).

1. Anticipation

To show that the subject matter claimed in the '985 and '214 patents are anticipated, Howmedica must show that a single prior art reference either explicitly or

[13]Whether a claim limitation is inherent is a question of fact. *IPXL Holdings, L.L.C. v Amazon.com, Inc.*, 430 F.3d 1377, 1380 (Fed. Cir. 2005)*; Med. Instrumentation & Diagnostics Corp. v. Elekta AB*, 344 F.3d 1205, 1220 (Fed. Cir. 2003).

inherently discloses each and every element of the claimed invention and that the prior art was in public use or on sale in this country more than one year prior to the date of the application for patent in the United States. At issue here is the sale, implantation, and dissemination of surgical protocol regarding Howmedica's HS-1 hip stem starting in January 1980. A parent application that eventually led to the issuance of the '985 and '214 patents was filed on April 19, 1982. Thus, to prove anticipation, Howmedica must demonstrate that the HS-1 prior art was in public use or on sale in this country prior to April 19, 1981.

According to Howmedica, the HS-1 hip stem is identical in all respects to hip stems alleged to infringe the patent-in-suit, was sold by Howmedica's predecessor, Osteonics, in January 1980, and was actually implanted in a patient in January 1980. Docket No. 110 at 16. Howmedica also asserts that surgical protocols describing the method for implanting HS-1 hip stems were also publicly available prior to April 19, 1981. *Id*. Contrarily, Tranquil argues that "[e]ven under the inherency doctrine, however, the HS-1 prosthesis does not anticipate the subject claims, as implantation surgeries using that prosthesis did not "necessarily" result in the claimed inventions, and specifically the claimed ration percentages of those inventions." Docket No. 104 at 17 (citing *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1269 (Fed. Cir. 1991).

Essentially, the issues here are: (1) whether the 70% and 90% limitations set forth

in claim 1of the '985 patent are inherently met and (2) whether the surgical protocols teach, explicitly or inherently, the 70% and 90% limitation in claim 2 of the '214 patent. This Court finds that there are genuine issues of material fact as to inherency and whether the HS-1 and associated protocol invalidate the claims of the '214 and '985 patents, which preclude granting summary judgment of invalidity.

2. Corroboration

Tranquil contends that there is insufficient corroboration because "mere witness testimony regarding the prior art and what it teaches is insufficient." Docket No. 104 at 18. Tranquil first asserts that Dr. Burnstein is not a "disinterested" witness because he has worked on a number of cases as an expert for Howmedica. *Id*. Tranquil also asserts that there is "no corroborating evidence that the HS-1 prostheses satisfied the 'transverse sectional dimensions' requirements of the subject claims . . . there are no records indicating when the HS1 tool samples . . . were manufactured . . . [and] Dr. Burnstein does not know when the size 9 HS-1 prosthesis . . . was first available." *Id*. Accordingly, Tranquil asserts that the "size 9 HS-1 may not even been prior art to the subject claims." *Id*. This Court finds that there are genuine issues of material fact which preclude granting summary judgment of noninvalidity.

3. Experimental Use

Tranquil also contends that, if experimental, the HS-1 prosthesis cannot act as an anticipating statutory bar to the subject claims." Docket No. 104 at 19. Tranquil asserts

that the "HS-1 sample stem located by Howmedica in this litigation was not a production model, but a 'lab piece' . . . certain information about the HS-1 prosthesis was maintained as confidential . . . [which is] relevant to the question of experimental usage.

Tranquil has not provided this Court with any evidence – only attorney argument – that the HS-1 prosthesis was experimental. "Unsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony." *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005). Such wholly conclusory assertions on a legal issue cannot carry Tranquil's burden on summary judgment. *See Biotec Biologische Naturverpackungen GmbH & Co. KG v. Biocorp, Inc.*, 249 F.3d 1341, 1353 (Fed. Cir. 2001).

VI. CONCLUSION

Based on the foregoing analysis, Howmedica's First Motion for Summary Judgment of Noninfringement (*Amended*) (Docket No. 97) is **GRANTED**. Tranquil's Motion for Summary Judgment of Direct, Literal Infringement of the Asserted Claims of the '985 Patent (Docket No. 103) is **DENIED**.

SO ORDERED.

DATED: March 28, 2007

S/ Allen Sharp
ALLEN SHARP, JUDGE
UNITED STATES DISTRICT COURT